SEP - 8 2000

K001766

510(k) SUMMARY
XGIF-N200H Gastrointestinal Videoscope

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject device

Name & Address of Manufacturer ;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	810047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5101 FAX 81-426-46-2786

2 Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc.
Address, Phone and Fax	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL (516)844-5688 FAX (516)844-5416

B. Device Name, Common Name

1. Device Name :	XGIF-N200H Gastrointestinal Videoscope and its associated accessories and Ancillary Equipment.
2. Common/Usual Name :	Endoscopic Video Information System
3. Classification Name :	21CFR 876.1500 Class II

C. Predicate Devices :

# K954451	EVIS-140 Series Scope
# K963033	BF-240/P240/1T240 Bronchovideoscope & Accessories
#K926514	EUS-20 System including accessories for GI
#K981543	LF-TP/DP Tracheal Intubation Fiberscope

D. Summary Description of the Device

1. Summary

The diagnosis and treatment of upper digestive tract using endoscope via oral insertion have been performed widely.

. But there are patients with difficulty to pass an endoscope through the esophagus or EC junction, because of stenosis, trismus, strong pharynx reaction. XGIF-N200H has been developed with narrowing the insertion portion to enable via nasal insertion for these patients.

XGIF-N200H has been developed so that it enables via nasal insertion and apply for such patients by thinning outer diameter, besides via oral.

Even though thinning outer diameter, this scope provided with biopsy channel, and resolution of this device are better than other gastrointestinal endoscope which already cleared 510(k) , so this device does not affect safety or efficacy for endoscopic surgery or diagnosis.

2. Design

"XGIF-N200H Gastrointestinal Videoscope" has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC 60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-2-18.

3. Materials

There are no new patient-contacting materials.

E. Intended Use of the device

These instruments have been designed to be used with an Olympus Video System Center, Light Source. Documentation Equipment. Video Monitor, Endo Therapy Accessories (such as a Forceps or Electrosurgical Unit) and ancillary equipment for transoral or transnasal observation and surgery within the upper digestive tract (including the esophagus, stomach and duodenum)

F. Technological Characteristics

This endoscope does not have special technological characteristics, when compared to the predicate device.

G. Reason for not requiring clinical data

When compared to the predicate devices, "XGIF-N200H Gastrointestinal Videoscope" does not incorporate any significant change for safety and efficacy to the predicate device. Therefore clinical data is not necessary for its evaluation of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Olympus Optical Co., Ltd.
c/o Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K001766
Olympus XGIF-N200H Gastrointestinal Videoscope
Dated: June 7, 2000
Received: June 12, 2000
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FDS

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001766

Device Name: XGIF-N200H Gastrointestinal Videoscope and its associated accessories and ancillary Equipment

Indications for Use:

The XGIF-N200H has been designed to be used with an OLYMPUS Video System Center, Light Source, Documentation Equipment, Video Monitor, Endo-Therapy Accessories (such as a Forceps or Electrosurgical Unit) and other ancillary equipment for transoral or transnasal observation and surgery within the upper digestive tract (including the esophagus, stomach and duodenum).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presciption Use ✓ OR Over-the Counter Use _____
(per 21CFR 801.109)

(Optional Format 1-2-96)

David G. Hyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001766